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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,290

03/03/2004

Frank S. D'Amelio SR.

45437

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09/04/2008

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

09/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/791,290	<b>Applicant(s)</b> D'AMELIO ET AL.	
	<b>Examiner</b> LEZAH W. ROBERTS	<b>Art Unit</b> 1612	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 7, 9, 11-13, 16, 17, 22, 24, 25 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 26 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

This Office Action is in response to the Request for Continued Examination filed June 11, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claims***

#### **Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

1) Claims 1, 9 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Romanowski et al (US 2005/0158252). The rejection is maintained.

#### **Applicant's Arguments**

Applicants submit that it would not have been obvious to one of ordinary skill in the art in view of Romanowski et al. to combine the claimed ingredients in an amount to inhibit inflammation of oral tissue as in claim 1. The rejection is based on randomly selecting certain components disclosed in Romanowski et al. and the reference provides no guidance or suggestion to combine the components in the claimed manner. Based on the disclosure in Romanowski et al., hundreds of potential compounds and compositions could be prepared by randomly picking and choosing selected components. The rejection relies on Applicants' disclosure to make the selection, and thus, does not establish prima facie obviousness. Furthermore, Applicants have found

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that each of the components show a particular function and provides a specific property to the composition when combined to provide an oral composition to inhibit inflammation. The enhanced performance of the specific combination of the plant components are exhibited by the claimed combination. Applicant further submits the bio-saponin is found to function as a natural surfactant which breaks down the outer layer of cells and other waxy layers, which enables the gota kola to function more effectively to promote lyses of bacteria. Bio-saponin also functions as a foaming agent and enhances the performance of the other components such as the Centipeda extract, coenzyme Q10, aloe vera, folic acid, and Vitamin E. Romanowski et al. clearly does not disclose or suggest these features or the claimed combination of the active components.

### Examiner's Response

In regards to holistic extract, Applicant discloses a holistic extract contains a water soluble fraction and an alcohol soluble fraction, yet Applicant does not appear to disclose what ratios or the procedure that is used to obtain the holistic extract of the instant claims. In regards to the combination of components, as asserted before by the Examiner, it is *prima facie* obviousness to select a known material based on its suitability for its intended use and the ingredients in the claims are disclosed by Romanowski et al. as agents that kill microorganisms, reduce inflammation and rebuild damaged tissue. Therefore it would have been obvious to combine these components

for their functional value. The suggestion for adding the components together is the recitation that the components may be included into the compositions. Although Applicant has argued that bio-saponin provides the compositions with enhanced activity due to its mechanism of action on the cells, Applicant has not shown any evidence of this action as suggested in the previous office action dated January 11, 2008, page 4. Furthermore Applicant does not recite the effective amount in which bio-saponin is needed to achieve the asserted function (see Remarks, page 11).

2) Claims 1-3, 7, 9, 11-13, 16, 17, 22, 24, 25 and 28-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Harrison (The Periodontal Solution: Healthy Gums Naturally) and Rice et al. (US 5,741,138). The rejection is maintained.

#### Applicant's Arguments

Applicant argues the combination of the cited patents and publications as a whole does not disclose or suggest the claimed composition and provide no teaching or suggestion to combine the components in the manner of the claimed invention. Close does not disclose or suggest a holistic extract of *Centipeda cunninghami* as in claim 1 or the extract in combination with the other active components. The combination of the claimed plant materials is not a random selection, but instead, a combination based on

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experimentation to provide the anti-inflammatory properties in the oral composition. The specific combination of components and the amounts of the components provide a moisturizing feel to the mouth compared to the drying or astringent feel of the prior compositions. The art of record provides no teaching or suggestion to combine the components in the claimed amounts or that the claimed components provide the properties of the present invention. The rejection is based on randomly selecting certain components from Close, Harrison and Rice et al. and clearly uses Applicants' disclosure as a guide to select the components and to combine them in the manner that is disclosed only in Applicants' specification. The Action provides no basis for the position that it would have been obvious to select the claimed components from the broad list of components in each of the cited patents to attain the claimed composition.

#### Examiner's Response

As mentioned above, Applicant discloses a holistic extract contains a water soluble fraction and an alcohol soluble fraction, yet Applicant does not appear to disclose what ratios or the procedure that is used to obtain the holistic extract of the instant claims. Close also discloses the extract is obtained from an aqueous alcoholic extract, therefore encompassing "holistic". The reference also suggests incorporating abrasives, solvents, humectants, detergents, binders, herbal actives (e.g. aloe vera ), essential oils (e.g. eucalyptus oil, peppermint oil), deodorizing agents (e.g. chlorophyll) and/or a suspension agents (e.g. hydrogenated castor oil). The secondary reference provides the functional value of components encompassed by these categories, thereby

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giving motivation as to why one of ordinary skill in the art would have used these components in conjunction with the compositions of Close. Furthermore it is *prima facie* obviousness to select a known material based on its suitability for its intended use. See MPEP 2144.07, which further supports the instant rejection.

### ***Allowable Subject Matter***

Claims 10 and 26 are allowable. The following is a statement of reasons for the indication of allowable subject matter: the claims appear to be allowable over the cited prior art because they provide specific weight percentages for each component. The prior art provides no motivation for combining all the recited components in the recited amounts.

Claims 1-3, 7, 11-13, 16, 17, 22, 24, 25 and 28-33 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612